MAR COR PURIFICATION
A Cantel Medical Company

BioPure HX2
Reverse Osmosis Water Purification System

APR 30 2014

510(k) Summary

Manufacturer: Mar Cor Purification, A Cantel Medical Company

Address: 14550 28th Avenue North
Minneapolis, MN 55447 USA
(800) 633-3080

Official Contact: Kinnari Shah, MS
Regulatory Affairs Specialist

Trade Name: **BioPure HX2**
Common Name: Water Purification System
Classification Name: Subsystem, water purification
Product Code: FIP
Device Class: II
Classification Reg: 876.5665

Mar Cor Purification has supplied the following information to the US Food and Drug Administration to support substantial equivalence of the BioPure HX2 Reverse Osmosis (RO) Water Purification System to other RO water purification systems currently cleared for sale in the U.S.

1. Device Description

The device is a water purification system that uses reverse osmosis to remove contaminants from water that is used to dilute dialysis concentrate to form dialysate for use in hemodialysis equipment. The key feature of BioPure HX2 RO system is that it consists of two trains (1st and 2nd pass) of membrane elements. Feed water enters the unit and is directed through a pump into the 1st pass RO membrane. The pump applies a high hydrostatic pressure that forces water from the concentrated (feed) side to the dilute (product) side of the RO membrane. The product water is then pumped directly through the 2nd pass membrane elements to further improve water quality of the final product water. As water flow across the membrane all types of water contaminants except

dissolved gasses are removed and the purified product water is then supplied to hemodialysis equipment.

The BioPure HX2 is capable of generating purified water that meets AAMI water quality requirements for hemodialysis at a minimum of 3 US gallons/minute (11.30 liters/min). It must be used with appropriate pre and post treatment units, including at a minimum carbon adsorption media pretreatment in order to remove chlorine/chloramines. Additional pre and post treatment requirements may vary and are dependent on the quality of the local feed water supply and individual facility requirements.

The BioPure HX2 system is designed to maintain low microbiological levels in the flow pathway through regular heat disinfection and chemical sanitization. Notable components and features of the BioPure HX2 include:

- Break Tank
- Immersion Heater
- 1st Pass RO Booster Pump
- 1st Pass RO membrane
- 2nd Pass RO Booster Pump
- 2nd Pass RO membrane
- Particle and Pyrogen Filter (Optional)
- Piping
- Water quality monitoring system
- Programmable logic controller (PLC)
- Heat disinfection and chemical sanitization capability
- Audible and visual alarms
- Automatic divert to drain mode upon start-up and anytime product quality parameters are not met.
- System control via a touch-screen user interface

2. Intended Use

The BioPure HX2 Reverse Osmosis water purification system is designed to purify pre-treated water using reverse osmosis for making dialysate for hemodialysis applications. The device is intended to be a component in a complete water purification system. It must be preceded by pre-treatment devices, and

may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. BioPure HX2 is intended for use in water rooms in a hospital, clinic, or dialysis center. The device includes an integrated heat disinfection process.

The BioPure HX2 is available two different double pass configurations that supply 5 gallons per minute (gpm) and 11 gpm. Version HX2P-05 is a double pass triple membrane RO that produces up to 5 gpm of product water. Version HX2P-11 is a double pass six membrane RO that produces up to 11 gpm of product water.

3. Comparison to Other Devices in Commercial Distribution Within the United States

The BioPure is equivalent in function and indications to the Mar Cor's (formerly Biolab Equipment Canada Ltd.) - 4400 HX Water purification system (K030348) and Mar Cor's Millenium HX Portable Reverse Osmosis water Purification System (K110578).

Both the subject and predicate devices have the same intended use, principle of operation and basic functions. All devices have equivalent indications for use and intended performance.

4. Summary of Non-Clinical Performance Data

Mar Cor Purification has provided testing to show that the BioPure HX2 is safe and effective for its intended use based on the requirements listed in FDA's Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis (May 1997) and the FDA recognized consensus standards - ISO 26722:2009 Water treatment equipment for hemodialysis applications and related therapies and ISO 13959:2009 Water for hemodialysis and related therapies. The following types of data were provided to FDA to support substantial equivalence to predicate devices and to demonstrate that the BioPure HX2 performs as intended.

- System and RO Membrane Performance
- Heat Disinfection Process Validation
- Chemical Sanitization Validation
- Material Compatibility and Biocompatibility
- Software Validation
- Electrical Safety and Electromagnetic Compatibility

- Risk Analysis

5. Conclusion

Mar Cor Purification has provided appropriate premarket notification information in the form of a 510(k) to support the substantial equivalence of the BioPure HX2 to legally marketed predicate devices. The information and performance data provided indicates that the BioPure HX2 is safe and effective for its intended use when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 30, 2014

Mar Cor Purification, Inc. - A Cantel Medical Company
% Kinnari Shah, MS
Regulatory Affairs Specialist
Medivators, Inc.
14605 28th Avenue North
Minneapolis, MN 55447

Re: K133149
Trade/Device Name: BioPure HX2
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 28, 2014
Received: March 31, 2014

Dear Kinnari Shah,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K133149

Device Name: **BioPure HX2**

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Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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